UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION THIS DOCUMENT RELATES TO: *The Montgomery County Board of County Commissioners et al. v. Cardinal Health, Inc., et al.*, Case No. 1:18-op-46326-DAP	MDL 2804 Case No. 1:17-md-2804 Judge Dan Aaron Polster

PLAINTIFF'S MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE CERTAIN OPINIONS OF PATRICK J. MARSHALEK

Defendant Kroger has proffered opinions from Dr. Patrick J. Marshalek, a psychiatrist practicing in West Virginia. In his current position, Dr. Marshalek provides inpatient, outpatient, consultative, and procedural services, including related to addiction. Dr. Marshalek's report consists of approximately four pages of substantive text. *See* Ex. A, 1/9/2023 Marshalek Tr., at 62:16–21; Ex. B, 12/12/2022 Marshalek Rep. Plaintiff seeks to exclude two categories of Dr. Marshalek's opinions because they are beyond his knowledge and experience: (1) those related to pharmacy practice and dispensing obligations; and (2) those related to the conduct of federal regulators, in particular the Drug Enforcement Administration (DEA), and whether federal regulators caused or contributed to the opioids catastrophe.

First, with respect to pharmacy practice, Dr. Marshalek opines: "[T]he pharmacists' scope of practice and situation downstream from the medical decision making and informed consent process prevent and limit their ability to question the legitimacy of prescriptions, and if they were ordered in the course of routine medical practice." Ex. A at 3. Dr. Marshalek also concludes his report with the related opinion: "To suggest that community pharmacies, or the pharmacists working for those community pharmacies, are responsible for the crisis of addiction is wrong." *Id.* at 6.

Dr. Marshalek should not be permitted to offer these opinions about pharmacy practice related to the dispensing of prescription opioids and the ultimate culpability of pharmacies for their role in the opioids catastrophe. Dr. Marshalek is not a pharmacist, has never dispensed a prescription opioid, has not worked in a pharmacy or studied pharmacy practice, and admitted in no uncertain terms that he is unfamiliar with pharmacies' dispensing obligations related to opioids. *See* Ex. A at 14:9–15, 16:1–11. Dr. Marshalek is unaware of even the most basic concepts and terms central to pharmacists' dispensing practices as they relate to opioids, such as corresponding responsibility, red flags, and due diligence. *See id.* at 16:16–26:4. Moreover, in forming his pharmacy-related opinions, Dr. Marshalek did not review any Kroger policies or procedures relevant to its own pharmacies' dispensing practices. The Court should not permit Dr. Marshalek's opinions on a topic so fundamental to this case and with which Dr. Marshalek is so wholly unfamiliar.

Second, Dr. Marshalek opines that "[t]he federal government could have limited the amount of opioids manufactured, changed how opioids were scheduled, changed the FDA indication of opioid use, used REMS programs or waiver requirements, or limited the manufacturers' ability to influence prescribing through marketing communications and other activities." Ex. B at 6.

Dr. Marshalek does not have the knowledge, experience, expertise, or any other basis to support his opinions regarding the role of federal regulators in overseeing the opioid industry and the hypothetical steps that these regulators could have taken to mitigate the harms caused by the opioid epidemic. Dr. Marshalek has never worked for DEA or the Food and Drug Administration (FDA). He did not know any specifics as to how DEA sets quotas or how FDA approves indications for drugs. *See* Ex. A at 31:22–33:16. Dr. Marshalek has not written about federal regulation of the opioid industry or reviewed testimony on this topic. *See id.* at 39:12–19, 40:15–18. Dr. Marshalek's experience as a DEA litigation consultant is limited to pill mill prosecutions and unrelated to DEA's overall regulation of the pharmaceutical industry. *See* Ex. C, Marshalek C.V., at 12. In short, he lacks the knowledge and experience to opine in any terms as to what "[t]he federal government could have" done to combat the

epidemic of opioid overdose deaths. Ex. B at 6. Dr. Marshalek's opinions about federal regulation of the opioid industry should also be excluded.

LEGAL STANDARD

To "testify in the form of an opinion," an expert witness must be qualified "by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. The Supreme Court has articulated the standard for admitting expert testimony in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), which "emphasize[s] the district court's role as the gatekeeper tasked with insulating juries from inadmissible expert testimony." *In re Nat'l Prescription Opiate Litig.*, No. 17-MD-2804-DAP, 2019 WL 3934597, at *1 (N.D. Ohio Aug. 20, 2019) (citations omitted). Testimony beyond a witness's expertise is inadmissible. *See Rheinfrank v. Abbott Labs., Inc.*, 680 F. App'x 369, 380 (6th Cir. 2017) (affirming limitation on testimony of medical experts to medical topics for which they were qualified); *Burgett v. Troy-Bilt LLC*, 579 F. App'x 372, 377 (6th Cir. 2014) (affirming exclusion of testimony of mechanical engineer with respect to biomechanical issues and human factors because expert had neither training nor experience in those fields); *see also, e.g.*, *Mathison v. Moats*, 812 F.3d 594, 597 (7th Cir. 2016) (prison doctor who was not a cardiologist was not qualified to testify about whether prisoner's troponin levels were within normal range). A witness may not bootstrap expertise in one field into admissible testimony on another, unrelated topic. *In re Welding Fume Prods. Liab. Litig.*, No. 03-CV-17000, 2005 WL 1868046, at *33 (N.D. Ohio Aug. 8, 2005) ("An expert may be highly qualified to respond to certain questions and to offer certain opinions, but insufficiently qualified to respond to other, related questions or to opine about other areas of knowledge."); *see also, e.g.*, *Levin v. Dalva Brothers, Inc.*, 459 F.3d 68, 78 (1st Cir. 2006) ("That a witness qualifies as an expert with respect to certain matters or areas of knowledge, does not mean that he or she is qualified to express expert opinions as to other fields."); *Nimely v. City of New York*, 414 F.3d 381, 399 n.13 (2d Cir. 2005) ("because a witness qualifies as an expert with respect to certain matters or areas of knowledge, it by no means follows that he or she is qualified to express expert opinions as to other fields"). In short,

while "the *Daubert* standard is liberal and does not require expert opinions to be bulletproof," "an expert's testimony should be excluded when it amounts to 'mere guess or speculation.'" *In re Nat'l Prescription Opiate Litig.*, 2019 WL 3934597, at *2, 5 (quoting *United States v. Lang*, 717 F. App'x 523, 534 (6th Cir. 2017), and *United States v. L.E. Cooke Co.*, 991 F.2d 336, 342 (6th Cir. 1993)). The party proffering the expert testimony bears the burden of demonstrating by a preponderance of proof that the expert's opinions are admissible. *See Nelson v. Term. Gas Pipeline Co.*, 243 F.3d 244, 251 (6th Cir. 2001).

ARGUMENT

Dr. Marshalek lacks both the knowledge and experience to testify about pharmacies' and pharmacists' dispensing of opioids. He also lacks the knowledge and experience to testify about federal regulation of the opioid industry. Dr. Marshalek's opinions on these two topics should be excluded because they amount to nothing more than speculation.

I. Marshalek Does Not Have the Knowledge or Experience That Would Permit Him to Offer Opinions Regarding Pharmacies' and Pharmacists' Dispensing of Opioids.

Dr. Marshalek offers expert opinions about the scope of the practice of pharmacy with respect to the dispensing of opioids that are well beyond his demonstrated knowledge and experience.

Dr. Marshalek has no meaningful experience in a pharmacy setting. His pharmacy practice experience is limited to a time during medical school, when Dr. Marshalek "volunteered in a pharmacy" to "packag[e] medications up" on a "weekly basis" over "a year or two." *See* Ex. A at 13:6–24. However, Dr. Marshalek did not dispense any medications, let alone prescription opioids, to patients as part of his pharmacy volunteer work. *See id.* at 14:9–15. Dr. Marshalek also lacks any knowledge of the concepts most fundamental to pharmacies' and pharmacists' dispensing practices as well as the legal obligations that govern them. This is evident from the following examples:

> Q. Have you ever heard the term "corresponding responsibility" in the context of pharmacies?
>
> A. Not that I'm aware of.

Id. at 16:16–19.

> Q. . . . Have you heard the term "red flags" in the context of a pharmacist dispensing opioids?
>
> A. Not that I recall.

Id. at 25:22–26:1.

> Q. . . . Have you heard the term "due diligence" in the context of a pharmacist dispensing opioids?
>
> A. Not that I can recall.

Id. at 26:2–5. Dr. Marshalek further could not recall writing "any articles about the obligations of pharmacies with respect to dispensing opioids prescriptions," or writing or speaking about "the obligations of pharmacies with respect to dispensing opioid prescriptions." *Id.* at 39:12–23.

"An expert's lack of experience in a particular subject matter does not render him unqualified so long as his general knowledge in the field can assist the trier of fact." *Dilts v. United Grp. Servs., LLC*, 500 F. App'x 440, 446 (6th Cir. 2012). But Dr. Marshalek also has no demonstrated knowledge in the practice of pharmacy. Dr. Marshalek's lack of "aware[ness]" of corresponding responsibility, and his inability to recall the concepts of red flags and due diligence, completely undermine his opinions related to pharmacies' dispensing of opioids. As this Court well knows, "corresponding responsibility," "red flags," and "due diligence" are fundamental as a duty, tool, and process (respectively) whereby pharmacists evaluate the legitimacy of opioid prescriptions pursuant to their obligations under the Controlled Substances Act. Dr. Marshalek does not seem to know this. When asked if it was his opinion "that pharmacies are not in a position to question the legitimacy of opioids prescriptions," Dr. Marshalek responded with "I'm just not sure how they can." *Id.* at 156:16–29.

If Dr. Marshalek is so unfamiliar with the ways in which pharmacists *can* question the legitimacy of prescriptions, and indeed does not even know *how* pharmacists evaluate prescriptions, this Court should not permit him to proffer opinions as to whether pharmacies' dispensing practices

"are responsible for the crisis of addiction." Ex. B at 3, 6. "[N]othing in his testimony suggests the sort of 'knowledge' on this point that the Rules require—only speculation, which is generally inadmissible." *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 671 (6th Cir. 2010). *Cf. In re Nat'l Prescription Opiate Litig.*, 589 F. Supp. 3d at 829, 831 (describing plaintiff's expert, medical doctor and addiction specialist Dr. Lembke, as having "extensive medical knowledge and expertise regarding 'red flags,'" and finding that her testimony about how CT3 pharmacy defendants contributed to the public nuisance of the opioid epidemic was "properly received into evidence at trial"). "The issue with regard to expert testimony is not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question." *Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994). Dr. Marshalek's qualifications evidently do not provide such a foundation for his answers to questions about pharmacy.

Courts in this Circuit regularly grant *Daubert* motions where otherwise qualified experts lack the knowledge or expertise required to proffer certain of their opinions. *See, e.g.*, *In re Aredia & Zometa Prods. Liab. Litig.*, 483 F. App'x 182, 189 (6th Cir. 2012) (affirming district court's exclusion of oral and maxillofacial surgeon's testimony where he "had never been involved in any clinical trials regarding the [bone disease] in question, had never served as a peer reviewer for any articles that involve [the disease], and had never conducted any research on [the disease] other than the two case reports" (internal citations omitted)); *United States v. Moss*, No. 21-CR-00169-PAB, 2022 WL 2789356, at *5 (July 15, 2022) (excluding expert opinion testimony related to purity of methamphetamine by doctor of pharmaceutics and pharmaceutical chemistry who "ha[d] no previous experience testifying as an expert regarding purity of controlled substances" and otherwise "reveal[ed] a lack of knowledge, skill, and experience in interpreting data related to the purity of methamphetamine"); *In re Dow Corning Corp.*, 541 B.R. 643, 649–50 (E.D. Mich. 2015) (excluding opinion of doctor specializing in internal medicine-pharmacology-toxicology who had not "established his knowledge or training as to autoimmune disease" in testimony about same). The court should

exclude Dr. Marshalek's opinions here especially because he possesses otherwise impressive and likely qualifying credentials; "where one person sees speculation, we acknowledge, another may see knowledge, which is why the district court enjoys broad discretion over where to draw the line." *Tamraz*, 620 F.3d at 672. Questioning the legitimacy of opioid prescriptions is a critical part of what pharmacists do, and Dr. Marshalek should not be permitted to offer any opinion about how pharmacists dispense opioids with such a demonstrated lack of knowledge about, and experience in, pharmacy practice.

In addition to his ignorance of general concepts central to pharmacists' dispensing of opioids, Dr. Marshalek also did not read or review Kroger's own policies and procedures that govern its pharmacies' and pharmacists' opioid dispensing practices.

> Q. Are you familiar with any policies or procedures that Kroger has used at any time regarding dispensing opioids?
>
> A. Not that I'm aware of.

Ex. A at 16:6–15.

> Q. Do you have any information at all about what Kroger did to ensure it was meeting any obligations that it or its pharmacists might have had prior to dispensing opioids in Montgomery County?
>
> A. Not that I'm aware of.

Id. at 26:15–20.

> Q. Have you reviewed any documents related to any Kroger policies or procedures regarding the dispensing of opioids?
>
> A. Not that I'm aware of.

Id. at 26:23–27:4 (objection omitted). Dr. Marshalek's lack of knowledge of Kroger's pharmacy practices, which knowledge he might have acquired while preparing his opinions in this litigation, underscores his ignorance of pharmacy practice in general. *Cf. In re Nat'l Prescription Opiate Litig.*, 589 F. Supp. 3d at 829 (noting that plaintiff's expert "[Dr.] Lembke testified she examined the evolving policies and procedures of each Pharmacy Defendant, over a period of time, and determined the policies

were ineffective or inadequate to detect 'red flags' that were well-known in the medical community at the given time" (footnote omitted)).

Accordingly, given his general lack of knowledge about pharmacy practice as well as his failure to do any Kroger-specific review of policies and procedures related to its pharmacy practice, Dr. Marshalek should not be permitted to offer any opinions about Kroger's pharmacies' and pharmacists' dispensing of opioids.

II. Marshalek Does Not Have the Knowledge or Experience That Would Permit Him to Offer Opinions Regarding Regulation of the Opioid Industry by Federal Agencies.

Dr. Marshalek is similarly out of his depth with respect to his opinions about the role of DEA, FDA, and other federal agencies that are responsible for regulating the opioid industry. In his report, Dr. Marshalek opines cursorily on several regulatory actions that DEA and FDA may take with respect to controlled substances. *See* Ex. B at 6 (briefly describing hydrocodone rescheduling, the FDA REMS program, and DEA buprenorphine waivers). However, Dr. Marshalek could not "recall the specifics" of *any* of these processes when questioned about them. *See* Ex. A at 31:6–10 (unable to recall the specifics of how opioids are scheduled by the federal government); *id.* at 31:22–33:1 (unable to recall the specifics of how the FDA decides which indications to approve for opioid medications); *id.* at 33:9–16 (unable to recall any opinions about "what quotas for manufacturing opioids DEA should have set at any time").

Dr. Marshalek further lacks any demonstrated knowledge about or experience with federal agencies' role as regulators of the opioid industry. *See id.* at 39:12–19 (unable to recall writing "any articles about the role of the federal government in regulating the opioids industry"); *id.* at 126:14–18 (Q: "Have you given testimony either by deposition or at trial at any time regarding the role of the federal government in regulating the opioids industry?" A: "I don't believe so."). And, as with Kroger's policies, Dr. Marshalek did not review any testimony of those who do have knowledge of, and experience in, federal regulation of the opioid industry. *See id.* at 40:15–18 (Q: "Have you reviewed

any depositions of any DEA or FDA witnesses in the opioids litigation?" A: "Not that I can recall.").

On several occasions, Dr. Marshalek was a DEA litigation consultant. He explained that this consulting work was limited to "criminal prosecutions," in which he provided "input regarding clinical practices and/or prescribers in clinic settings." *Id.* at 28:16–29:3. More specifically, Dr. Marshalek provided consultation in criminal cases brought by the government against physicians running opioid "pill mill[s]" to evaluate whether their prescribing habits were suspicious. *See id.* at 119:5–15. Dr. Marshalek's expertise in these cases was to opine about the pill mill physicians' prescribing practices related to pain management, addiction, psychiatry, and primary care. *See* Ex. C at 12. This limited experience, however, has no bearing on the role of federal agencies in regulating the opioid industry at large and provides no basis for the opinions Dr. Marshalek offers here.

Because Dr. Marshalek has no demonstrated knowledge of or experience in the ways in which federal agencies regulate the opioid industry, he should not be permitted to opine about the steps that federal regulators "could have" taken "to limit the overall amount of prescriptions that ultimately contributed to the epidemic of overdose deaths." *See* Ex. B at 6 (footnote omitted) (opining that the federal government "could have" taken several steps, the details of which he previously could not recall anything about). One of Dr. Marshalek's final conclusory opinions seems to place all responsibility for the opioid epidemic squarely on federal agencies while absolving prescribers, pharmacists, and pharmacies: "Far upstream from the busy prescriber, pharmacist, and community pharmacy sat those with power and ability to limit the overall amount of prescriptions that ultimately contributed to the epidemic of overdose deaths." *Id.*[1] But, again, Dr. Marshalek does not have any knowledge or experience to support his opinion about how federal agencies could have implemented these limitations

[1] Dr. Marshalek has but one citation in support of this proposition: Humphreys et al., *Responding to the Opioid Crisis in North America and Beyond: Recommendations of the Stanford-Lancet Commission*, 399 Lancet 555–605 (2022). Plaintiff's expert Dr. Lembke is a co-author of this report. Among other things, the recommendations comment on the pharmaceutical industry's success at "regulatory capture—i.e., getting corporate interest prioritized over the public interest." *Id.* at 570. Nowhere does the report echo the proposition for which Dr. Marshalek cites it.

or, more broadly, how federal agencies regulate the opioid industry. The distinction between an expert's knowledge of their own practice and regulatory standards potentially tangential to that practice is often parsed in this Circuit. *See, e.g.*, *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, No. 18-CV-01509-EAS, 2020 WL 6605612, at *10 (S.D. Ohio Sept. 11, 2020) (granting plaintiff's motion to exclude opinion about the adequacy of product warnings "from a regulatory or legal perspective" by hernia surgeon where he "had no experience drafting" the relevant warnings and "no knowledge of the[ir] requirements"). Dr. Marshalek similarly lacks the knowledge to opine on federal regulatory oversight of the opioid industry, and his opinions are at best uninformed speculation. *See Tamraz*, 620 F.3d at 671. He should not be permitted to offer them.

Because Dr. Marshalek has no knowledge of, or experience in, pharmacy practice and federal regulation of the opioid industry, his opinions related to (1) pharmacies' and pharmacists' opioid dispensing practices, and (2) federal agencies' regulation of the opioid industry should be excluded.

Dated: February 8, 2023

Respectfully submitted,

/s/Peter H. Weinberger

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CERTIFICATE OF SERVICE

I hereby certify that on February 8, 2023, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system and may be obtained by using the CM/ECF system. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF system.

/s/Peter H. Weinberger
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